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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,222	07/27/2001	Dan M. Granoff	CHOR-001	9605
24353	7590	03/22/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/917,222

**Applicant(s)**

GRANOFF ET AL.

**Examiner**

Robert A. Zeman

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 28-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-38 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8-15-01.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's election without traverse of Group I in the paper filed on 12-5-2003 is acknowledged. Claims 1-38 are pending. Claims 16-19 and 28-38 are withdrawn from consideration. Claims 1-15 and 20-27 are currently under examination.

#### ***Specification***

The use of trademark has been noted in this application (see pages 25 and 53 for examples). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification is objected to for containing incomplete ATCC deposit information (see pages 51 and 69).

#### ***Claim Objections***

Claim 11 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 recites the limitation that the serosubtype of the first, second and third species is different. This limitation is present in the parent claim.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing neutralizing antibodies comprising administering to an animal a first preparation of microvesicles (MVs) from a first *Neisseria meningitidis* species, a second preparation of MVs (and/or Outer membrane vesicles) from a second *Neisseria meningitidis* species and optionally a third preparation of MVs and/or outer membrane vesicles (OMVs) from a third *Neisseria meningitidis* species wherein the serotype or serosubtype of each preparation is different, does not reasonably provide enablement for using the aforementioned preparations to elicit broad spectrum protective immunity against *Neisseria meningitidis* and diseases caused by *Neisseria meningitidis* species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The rejected claims are drawn to the prophylactic use of compositions comprising MVs and optionally OMVs from *Neisseria meningitidis* species. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed use of the claimed deletion provides any sort of protective immunity in any model system that can be extrapolated to humans or other mammals. Applicant describes methods of

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producing antibodies (i.e. antisera) that is bactericidal *in vitro* but fails to demonstrate the claimed method provides protective immunity (broad spectrum or otherwise) in any animal system other than ruminants. Moreover, the specification is silent on what “diseases” can be prevented by the claimed methods. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for methods of eliciting broad-spectrum protective immunity against *Neisseria meningitidis* and diseases caused by *Neisseria meningitidis* species.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the reference to the “third *Neisseria meningitidis* species” and the “third preparations” in the 4<sup>th</sup> paragraph of the claim. It is unclear what said terms are referring to since only 2 “preparations” and “species” were recited in the previous portion of the claim. This discrepancy renders claims 5 and 6 confusion since both claims recite the term “third preparation”.

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Claim 1 and 14 are rendered vague and indefinite by the phrase “a disease caused by more than one strain of *Neisseria meningitidis* species”. It is unclear what is meant by said term. Is Applicant claiming that said disease has to have more than one etiological agent? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 7 is rendered vague and indefinite by the use of the phrase “a disease at least for strains of *Neisseria meningitidis* species”. It is unclear what is meant by said phrase.

Claim 9 is rendered vague and indefinite by the phrase “a disease caused by at least four strains of *Neisseria meningitidis* species”. It is unclear what is meant by said term. Is Applicant claiming that said disease has to have four etiological agents? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 21 recites the limitation "excipients" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the adjuvant" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites improper Markush language. When the phrase “selected from the group consisting of” is used, the ultimate member of the group must be preceded by the conjunction “and”.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman  
March 18, 2004



MARK NAVARRO  
PRIMARY EXAMINER